Wendy R. Fleishman (N.Y. Bar No. 2500429)
(*pro hac vice* application forthcoming)
wfleishman@lchb.com
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, NY 10013
Telephone: 212.355.9500
Fax 212. 355.9592

Fabrice N. Vincent (CA Bar No. 160780)
fvincent@lchb.com
Ian R. Bensberg (application for admission
pro hac vice forthcoming)
ibensberg@lchb.com
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: 415.956.1000
Facsimile: 415.956.1008

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ALISSA THOMAS, individually and on behalf of her minor child A.K.,

Plaintiffs,

v.

ABBOTT LABORATORIES INC.,

Defendant.

CIVIL ACTION

Case No. 3:22-cv-2971

COMPLAINT

DEMAND FOR JURY TRIAL

1. Plaintiffs bring this action complaining of Defendant as follows, based on personal knowledge and their counsels' investigation.

I. INTRODUCTION

2. This is an action to redress the injuries suffered by Plaintiff Alissa Thomas and her minor daughter, Plaintiff A.K., who has spent the majority of her life fighting against the harm caused by bovine-milk based (or "cow-based") infant formula manufactured, marketed, and sold by Defendant Abbott Laboratories Inc. ("Abbott"). Necrotizing enterocolitis ("NEC") is a potentially fatal disease that largely affects low birth-weight babies who are fed cow-milk based formula. Plaintiff A.K., a prematurely born, low birth-weight baby, was fed Defendant's cow-milk based Similac products and developed NEC as a result.

3. Plaintiffs bring claims against Defendant arising from Defendant's negligent, willful, and wrongful misconduct and omissions in connection with the design, development, manufacture, testing, packaging, promotion, marketing, distribution, and labeling of its cow-milk based formula.

B. THE PARTIES

4. Plaintiffs reside in San Francisco, California. Plaintiff A.K. is Plaintiff Knight's natural daughter, born to Plaintiff Knight in 2018.

5. Defendant Abbott Laboratories, Inc. is a corporation incorporated under the laws of the State of Illinois with its principal place of business in Abbott Park, Illinois.

C. JURISDICTION

6. This Court has jurisdiction under 28 U.S.C. § 1332(d) because complete diversity exists between Plaintiffs, citizens of California, and Defendant, a citizen of Illinois, and the matter in controversy, exclusive of interest and costs, exceeds $75,000.

7. This Court has personal jurisdiction over Defendant because Defendant markets, promotes, distributes, and sells cow-milk based formula in California, and Plaintiffs' claims arise out of Defendant's contacts with California.

D. VENUE

8. Venue is proper in this District under 28 U.S.C. § 1391(b) because Plaintiffs reside

in this District. Plaintiff A.K. was fed Defendant's cow-milk based formula in this district. Therefore, a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District.

E. DIVISIONAL ASSIGNMENT

9. Assignment to this division is proper under Civil Local Rules 3-2(c) and (e) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in the City and County of San Francisco.

II. BACKGROUND

A. The Science

10. Scientific research has demonstrated strong links between cow-milk based infant formula and NEC in premature infants.

11. More than thirty years ago, in 1990, a prospective multi-center study on 926 preterm infants found that NEC was 6 to 10 times more common in exclusively formula-fed babies than in those fed breast milk alone, and three times more common than in those who received formula plus breast milk. Lucas A, Cole T. Breast milk and neonatal necrotising enterocolitis. Lancet 1990; 336: 1519–1523.

12. A study published in 2010 established that when premature babies were fed an exclusive diet of mother's milk, donor milk, and/or human milk fortifier, they were 90 percent less likely to develop surgical NEC. Sullivan, S., et al., An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotising Enterocolitis than a Death of Human Milk and Bovine Milk-Based Products. Journal of Pediatrics 2010; 156:562-7.

13. In 2011, the U.S. Surgeon General published a report titled "The Surgeon General's Call to Action to Support Breastfeeding," warning that, "[f]or vulnerable premature infants, formula feeding is associated with higher rates of [NEC]." U.S. Department of Health and Human Services. The Surgeon General's Call to Action to Support Breastfeeding. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2011, p. 1.

14. In 2012, the American Academy of Pediatrics issued a policy statement that all premature infants should be fed exclusively a human milk diet because of the risk of NEC

associated with the consumption of cow-milk based formula. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk. … If the mother's own milk is unavailable … pasteurized donor milk should be used." Breastfeeding and the Use of Human Milk. Pediatrics 2012; 129:e827-e841.

15. Another study published in 2013 reported: "T[t]his is the first randomized trial in [extremely premature] infants of exclusive [human milk] vs. [preterm formula]. The significantly shorter duration of [total parenteral nutrition] and lower rate of surgical NEC support major changes in the strategy to nourish [extremely premature] infants in the [neonatal intensive care unit or] NICU." Cristofalo, E.A., et al., Exclusive Human Milk vs Preterm formula: Randomized Trial in Extremely Preterm Infants. J Pediatr 2013 Dec; 163(6): 1592-1595.

16. "It is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Good, Misty, et al., Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis. Expert Rev Clin Immunol. 2014 July; 10 (7): 875-884. The same study noted, "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies. The typical patient who develops NEC is a premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and up to 30% of infants will die from this disease." (Internal citations omitted.) Further, "[a] wide variety of feeding practices exist on how to feed the premature infant in the hopes of preventing [NEC]. … The exclusive use of human breast milk is recommended for all premature infants and is associated with a significant decrease in the incidence of NEC." (Internal citations omitted.)

17. Yet another study published in 2014 reported, "An exclusive human milk diet, devoid of [cow milk]-containing products was associated with lower mortality and morbidity in [extremely premature] infants without compromising growth and should be considered as an approach to nutritional care of these infants." Abrams, Steven, et al. Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products. Breastfeeding Medicine. 2014, Nov. 4, 9(6):281-286.

18. A 2016 study supported previous findings that an exclusive human milk diet in

extremely premature infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions with multiple years of follow-up using an exclusive human milk diet, and was a very large study. The authors concluded: "[t]he use of an exclusive [human milk] diet is associated with significant benefits for extremely premature infants" and, "while evaluating the benefits of using an exclusive [human milk]-based protocol, it appears that there were no feeding-related adverse outcomes." Hair, et al., Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet. Breastfeeding Medicine 2016, 11-2.

19. A study published in 2017 reported: "[Human milk] has been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC. Two [randomized clinical trials] on preterm infants weighing between 500 and 1250 g at birth compared the effect of bovine milk-based preterm infant formula to [mother or donor milk] on the incidence of NEC. Both trials found that an exclusive [human milk] diet results in a lower incidence of NEC."

20. A systematic review that evaluated the effect of cow milk-based formula on health outcomes for preterm infants also determined that cow milk-based formula significantly increases the risk of NEC. Shulhan, Jocelyn, et al. Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products. ASN. ADV Nutr 2017; 8:8—0-91.

B. <u>The Marketing</u>

21. Notwithstanding strong scientific and medical evidence establishing the serious danger that cow-milk based formula poses for premature infants, Defendant Abbott has marketed its cow-based products as equally safe alternatives to breast milk, and indeed has promoted its products as necessary for additional nutrition and growth. Defendant Abbott has specifically marketed its cow-based formula as necessary to the growth and development of premature infants, when in fact its products pose a known and substantial risk to these babies.

22. Defendant Abbott has attempted to "hook" parents on formula by offering free samples and other blandishments in baskets given to parents in hospitals and medical clinics. The goal is to create brand loyalty and the appearance of "medical blessing" so that parents continue

to use Defendant Abbott's products to feed their babies after they leave the NICU, at great expense to the parents, and substantial profit to Defendant Abbott.

23. Defendant Abbott's practice of trying to get parents to choose formula over breast milk goes back decades. The company has for decades promoted its products as healthier, necessary for adequate nutrition, and the choice for the modern, sophisticated mother. Its advertising has at times attempted to portray breastfeeding as an inferior, less sophisticated choice.

24. The World Health Organization (WHO) and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address the international marketing of breast-milk substitutes. The World Health Director concluded the meeting with the following statement: "In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement." Baumslag & Michels, 1995, p. 161. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly (WHA) developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, and prohibited any advertising or promotion of breast milk substitutes to the general public. The Code specifically prohibited advertising in Article 5, Section 1: "There should be no advertising or other form of promotion to the general public." The International Code of Marketing of Breast-milk Substitutes. Geneva: World Health Organization, p.16 - 20 (1981).

25. Defendant Abbott has acknowledged and pretended to endorse the Code. Nonetheless, Defendant Abbott has systematically violated the Code's most important provision: "There should be no advertising or other form of promotion to the general public." Advertising of cow-based infant formula has remained pervasive in the United States until today, including Defendant Abbott's advertising.

26. In the World Health Organization's 2018 Status Report on this issue, it was noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status

Report states that "a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes," noting that in 2014, the global sales of breast-milk substitutes amounted to US $44.8 billion and "is expected to rise to US $70.6 billion by 2019." Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018.

27. "Since the late 19th Century, infant formula manufacturers have encouraged mothers to substitute formula for breastmilk." Rosenberg KD, Eastham CA, Kasehagen LJ, Sandoval AP. Marketing infant formula through hospitals: the impact of commercial hospital discharge packs on breastfeeding. Am J Public Health. 2008;98(2):290-295.

28. One study estimated that formula manufacturers spent $4.48 billion on marketing and promotion in 2014. Baker, P, et al, Global trends and patterns of commercial milk-based formula sales: is an unprecedented infant and young child feeding transition underway? Public Health Nutrition, 2016.

29. Another study found that direct-to-consumer advertising increased request rates of brand choices and the likelihood that physicians would prescribe those brands. Parker, R. S., & Pettijohn, C. E. (2003). Ethical considerations in the use of direct-to- consumer advertising and pharmaceutical promotions: The impact on pharmaceutical sales and physicians. Journal of Business Ethics, 48, 279-290.

30. Yet another study found that exposure to infant feeding advertising has a negative effect on breastfeeding initiation. Merewood A, Grossman X, Chaudhuri J, Sadacharan R, Fein SB. Exposure to infant feeding advertising during pregnancy is associated with feeding decisions postpartum. Paper presented at American Public Health Association 138th Annual Meeting & Exposition; November 2010; Washington, DC.

31. In a study on infant feeding advertisements in 87 issues of Parents magazine, a popular parenting magazine, from the years 1971 through 1999, content analysis showed that when the frequency of infant formula advertisements increased, the percentage change in breastfeeding rates reported the next year generally tended to decrease. Stang J, Hoss K, Story M. Health statements made in infant formula advertisements in pregnancy and early parenting

magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.

32. The Stang study also found that infant formula company websites, printed materials, coupons, samples, toll-free infant feeding information lines, and labels may mislead consumers into purchasing a product that appears equivalent or superior to human milk. This may induce reliance on a biased source for infant feeding guidance. Stang J, Hoss K, Story M. Health statements made in infant formula advertisements in pregnancy and early parenting magazines: a content analysis. Infant Child Adolesc Nutr. 2010;2(1):16-25.

33. Defendant Abbott has designed and implemented a systematic, powerful, and misleading marketing campaign to deceive parents into believing that: (1) cow-milk formula and fortifiers like Similac are safe; (2) cow-milk products like are equivalent or even superior substitutes for breastmilk; (3) physicians consider cow-based products like a first choice; (4) the decision to breastfeed or to use cow-based formula products is a matter of personal preference merely, with no objective scientific criteria; and (5) cow-based formula are necessary for the growth of and are perfectly safe for premature infants.

1. Defendant Abbott's Marketing

34. The very name "Similac" is misleading, suggesting that it is *simi*lar to milk produced by human *lac*tation. That suggestion is false.

35. For example, one author found an advertisement for a Similac product on the back cover of the April 2004 issue of American Baby Magazine, reproduced below, that made repeated comparisons of cow-based formula to breast milk; the ad used the phrase "like breastmilk" six times. Broussard Hyderkhan, A, Mammary malfunction: a comparison of breastfeeding and bottle feeding product ads with magazine article content, 2005.

36. In addition to perpetuating the myth that Similac products are "like breastmilk," Defendant Abbott has also deceived the public into believing that physicians believe Similac products are an ideal choice for babies.

37. Beginning in 1989, Defendant Abbott began using claims in its advertising that Similac products were the "first choice of more physicians."

38. A plain interpretation of this claim is that physicians believe Similac products are the "first choice" even in preference to breastmilk.

39. Beginning in 1995, Defendant Abbott began a heavy marketing campaign featuring the claim "1st choice of Doctors" on all its infant formula product labels.

40. A marketing report commissioned by Defendant Abbott in March 1998 summarized consumer reactions to several advertising pamphlets for Similac products. The "1st Choice of Doctors" claim scored highest in terms of consumers' likelihood of purchase. The

report concluded, "Doctor recommendations and the 'science' behind the formula appeared to drive purchase interest for this concept, as well as the other concepts tested." Use of similar pieces emphasizing the same claim was "highly recommended."

41. Defendant Abbott released an ad called "The Mother 'Hood" that frames the choice between breastmilk and Similac products as a matter of personal preference, a debate which, while heated, is ultimately conducted by parents who simply wish the best for all children. The advertising conceals the fact that the "debate" is a false one, manufactured by companies like Defendant Abbott for their own promotional purposes. www.youtube.com/watch?v=JUbGHeZCxe4.

42. Another advertisement by Defendant Abbott, titled "The Judgment Stops Here," a documentary-style ad, likewise shows parents coming together, putting aside judgment of each other's choices. The ad is deceptive, however, and violative of the Code, because it puts breast milk and formula on an even playing field, and attempts to chastise any opinion that the question is not merely one of personal choice and but clear scientific evidence. In other words, the ad attempts to insulate Similac products from criticism or judgment, when criticism is wholly appropriate from a scientific standpoint.

43. Another ad by Defendant Abbott for a Similac product states, "[W]hen you are ready to turn to infant formula, but you don't want to compromise, look to Pure Bliss by Similac. It's modeled after breast milk." www.youtube.com/watch?v=kRaHiTMyYXs.

44. Moreover, Defendant Abbott has also attempted to market its Similac products specifically to premature infants—the very children at highest risk from their use.

45. In 1978, Defendant Abbott began marketing "Similac 24 LBW" specifically for premature infants, claiming that the product was "introduced to meet the special needs of premature infants."

46. In 1980, Defendant Abbott began marketing "Similac Special Care," claiming it was the first low-birth-weight, premature infant formula with a composition designed to meet fetal accretion rates.

47. In 1988, Defendant Abbott began marketing "Similac Special Care With Iron,"

claiming it "was the first iron-fortified formula for premature and low-birth-weight infants introduced in the US."

48. As of 2016, Defendant Abbott marketed and sold seven products specifically targeting "Premature/Low birth-Weight Infants," including six Similac products.

49. Defendant Abbott specifically targets parents of premature infants in its marketing. For example, a Google search for "feeding preemies formula" reveals among first-page results a paid advertisement for Similac products, with the heading "For Babies Born Prematurely." The ad states, "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." The advertisement further claims that the product is "pediatrician recommended," "#1 brand fed in Hospitals" and "backed by science." The advertisement makes no reference to the specialized need pre-term infants have for human breast milk, and makes no mention of the risk of developing NEC.

50. At all relevant times, Defendant Abbott maintained "similac.com," website directed at parents choosing formula products. The website states, "Need help choosing the right formula for your baby? Our Formula Finder can walk you through it." The website includes the prompt, "Was your child born prematurely?" If the parent clicks "yes," the website directs the parent to a page promoting Similac products.

51. There is no mention of the risk of NEC. The website expressly and implicitly represents that Defendant Abbott's cow-based formula are safe for use with premature infants. This promotion is false and misleading.

52. Another advertisement by Defendant Abbott states "whether you choose to formula feed or, to supplement breast feeding with formula, you can be confident in the nourishment of Similac." www.similac.com/why-similac.html. The representation to parents that they can be "confident" is directly contradicted by studies that indicate the cow-based formula is dangerous to premature infants. The ad is false and misleading.

53. Defendant Abbott's website also features reviews from parents whose premature infants were in the NICU, discussing how wonderful and safe the products are. There are no

reviews discussing NEC. It is therefore likely that these reviews are curated by Defendant Abbott to present a misleading picture of unanimous endorsement of its products.

54. CBS News reported that Defendant Abbott paid so-called "mommy bloggers" for positive reviews of Similac products. https://www.cbsnews.com/news/abbott-pays-bloggers-for-positive-reviews-of-its-similac-app.

C. Plaintiffs' Use of Defendant Abbott's Products

55. Plaintiff A.K. was born extremely premature at 24 weeks, 2 days of gestation, weighing 1 pound, at San Francisco General Hospital in San Francisco, California. Within the first days of her life, Plaintiff A.K. was fed Defendant Abbott's Similac product. As a result, Plaintiff A.K. developed NEC, requiring intestinal surgery and other substantial and costly medical interventions.

56. Within a week of her birth, Plaintiff A.K. was transferred from San Francisco General Hospital to the NICU at USCF Medical Center at Mission Bay, where she stayed for more than six months.

57. Before Plaintiff A.K. was fed Defendant's products, Plaintiff Knight was exposed to and relied on false marketing from Defendant that its cow-milk based formula is safe and necessary to the growth and nutrition of premature infants.

FIRST CAUSE OF ACTION
Negligence Products Liability

58. Prior to their use by Plaintiffs, Defendant was aware, or should have been aware, that its cow-milk based formula are not safe for use in premature infants, yet it took no steps to prevent their use in such a situation.

59. Defendant foresaw or should have foreseen that its cow-milk based formula would be used as they were in the case of Plaintiff A.K., and knew or should have known that such use would significantly increase the risk of NEC in Plaintiff A.K., yet it took no steps to prevent such use.

60. Defendant's cow milk -based formula were not safe to be used in the case of Plaintiff A.K., and Defendant knew or should have known that its cow-based formula was unsafe

to be fed to a preterm, low birth weight infant, yet it failed to provide any instructions or guidelines on when and how its formula would be safe to use in a premature infant like Plaintiff A.K.

61. Defendant has marketed its cow-based formula as safe and beneficial for premature infants like Plaintiff A.K.

62. Defendant has promoted its cow-based formula for extremely premature infants and claims the formula increases the baby's weight and caloric intake, and that the formula are more beneficial than harmful.

63. Defendant has advanced the false premises to parents, physicians, and other healthcare providers that human milk is not sufficient to meet the nutritional needs of premature infants, and that its cow-based formula are necessary as a substitute for or supplement to human milk.

64. Scientific research has unequivocally established the dangers of Defendant's cow-based products in causing NEC in premature infants, yet Defendant did nothing to change its product, packaging, guidelines, instructions, or warnings.

65. Scientific studies show Defendant's cow-based formula should not be sold for use in extremely premature infants, yet Defendant continued to market and sell cow-based formula knowing it would be used by infants like Plaintiff A.K. and knowing it would significantly increase the risk of NEC in extremely premature infants like Plaintiff A.K.

66. Defendant knew or should have known that its cow-based formula would be used in the way they were used with Plaintiff A.K.

67. The use of cow-based formula was extremely dangerous and caused an unreasonably high risk that Plaintiff A.K. would develop NEC, yet Defendant provided no detailed instructions or warnings to prevent or alter the way its products were used.

68. Despite learning that cow-based formula are linked to NEC, Defendant failed to properly collect data from doctors and hospitals in order to develop evidence based strategies, instructions, and warnings to reduce or prevent its products from causing NEC.

69. Despite learning that cow-based formula are linked to NEC, Defendant took no

steps to determine whether and how that link was causal.

70. In the alternative, Defendant learned that cow-based formula causes NEC in premature infants, yet did nothing to change its products, packaging, guidelines, instructions or warnings.

71. Despite knowing that cow-based formula causes NEC in premature infants, Defendant did not conduct any testing, undertake to have others conduct testing and studies, or do any data analysis or research to determine when cow-based formula should not be used or when and how cow-based formula are safe for use.

72. Despite knowing that cow-based formula causes NEC in premature infants, Defendant did not contact the FDA to inform the agency of this fact.

73. Plaintiff A.K.'s parents, physicians, and other healthcare providers were never told that cow-based formula could cause Plaintiff A.K. to develop NEC.

74. Plaintiff A.K.'s parents, physicians, and other healthcare providers were never told that cow-based formula could and would cause Plaintiff A.K. to suffer long term, devastating maladies, as Plaintiff A.K. has and will.

75. Plaintiff A.K.'s parents, physicians, and other healthcare providers were not told of the studies showing cow-based formula like cow-based formula was extremely dangerous to Plaintiff A.K.

76. Plaintiff A.K.'s parents, physicians, and other healthcare providers were not told of the studies showing that human donor milk was safer for Plaintiff A.K. than cow-cased products.

77. Plaintiff A.K.'s parents, physicians, and other healthcare providers were not told of the studies showing that an exclusive human milk diet is sufficient to meet all growth and nutritional goals of premature infants.

78. Despite knowing that cow-based formula causes NEC and long term adverse effects in premature infants, Defendant did not recommend or require discussion by hospitals, NICUs, or physicians of the risks of NEC and long term maladies with parents.

79. Despite knowing that cow-based formula causes NEC, as well as serious and devastating long term illnesses and adverse effects on growth and development, as it has in

Plaintiff A.K., Defendant did not contact the FDA, NICUs, hospitals, or physicians to inform them that cow-based formula are linked to or causes NEC and these long term consequences

80. Defendant knew or should have known that its cow-based premature infant products would be used, as they were, on extremely premature infants like Plaintiff A.K., yet it failed to properly warn hospitals, NICUs, doctors, parents, or consumers that its cow-based formula significantly increase the risk of NEC and long term adverse medical and developmental consequences in these babies; and are unsafe or contraindicated for extremely premature infants and low birth-weight babies like Plaintiff A.K.

81. Defendant's warnings and instructions for its cow-based formula are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn that cow-based formula significantly increases the risk of NEC and its sequelae, nor provide any details on how to avoid such harm.

82. Defendant failed to:

a. provide a warning or instruction that parents need to be provided an informed choice between the safety of human milk versus the dangers of cow-based formula;

b. provide proper instructions, guidelines, studies, or data on when and how to feed cow-based formula to premature infants in order to decrease the risk of NEC;

c. provide instructions to parents and physicians that cow-based formula carries a significant risk of NEC and its long term sequelae;

d. provide a prominent "black box"-type warning that cow-based formula are known to significantly increase the risk of NEC and its sequelae when compared to human milk in premature infants and in low birth weight infants;

e. provide well researched and well established studies linking cow-based products to NEC and its long term sequelae in premature infants and low birth-weight infants;

f. cite to or use up-to-date medical data on the proper and safe use of cow-based formula;

g. warn physicians and other healthcare providers of the extreme risk associated with feeding premature infants and low birth weight infants cow-based formula,

which, had physicians and other healthcare providers known of it, would have induced physicians and other healthcare providers not to use cow-based formula with Plaintiff A.K.;

h. send out "Dear Doctor" letters warning of the risks of NEC, and provide current scientific research and data to better guide hospitals and physicians to better care for the extremely premature infants;

i. advise physicians and other healthcare providers that cow-based formula are not necessary to achieve growth and nutritional targets for premature infants;

j. advise physicians and other healthcare providers that human milk is superior to cow-based products with regard to the overall health of a premature infant; and/or

k. take adequate measures to warn despite knowing that parents were not being warned of the risk of NEC by their physicians.

83. Defendant's massive marketing campaign as detailed in previous paragraphs has had the effect of: (1) diminishing the ability of parents to intelligently resist the advice of a healthcare provider to give formula; (2) diminishing parents' desire and understanding of the importance of breastfeeding; (3) diminishing the relationship between physicians and patients relative to nutritional decision-making; (4) making it more difficult for a physician to persuade parents to breastfeed; and (5) making it easier and more economically viable for hospitals to feed premature infants instead of donor milk or human milk-derived fortifiers.

84. As a result of the inadequacy of the warnings and the pervasive marketing suggesting the safety and necessity of cow-based formula, Plaintiff A.K. was fed Similac, which caused him to develop NEC and ultimately suffer significant long-term medical problems and developmental delays.

85. Defendant owed a duty of care to the children to whom its cow-based formula were targeted.

86. As a direct and proximate result of Defendant's breach of duty in the design, development, manufacturing, labeling, advertising, and sale of their cow-based formula, Plaintiff A.K. suffered severe medical injuries and long term damages that are yet to be determined. Plaintiff Knight has expended and continue to expend significant sums for Plaintiff A.K.'s care

and treatment.

87. Defendant's products' defective design proximately caused Plaintiff A.K.'s NEC, and proximately caused Plaintiff A.K.'s long term medical and developmental problems.

SECOND CAUSE OF ACTION
Strict Products Liability

88. Defendant was aware, or should have been aware, that its cow-based formula are not safe for use in premature infants like Plaintiff A.K., yet it took no steps to prevent their use in such a situation.

89. Defendant's cow-based formula are defectively designed as alleged above.

90. Defendant's cow-based formula are unreasonably dangerous as alleged above.

91. Over the last several years, scientific data and well researched studies have concluded that cow-based products carry unreasonable risks of NEC, which far outweigh the products' benefits.

92. Defendant's cow-based formula's risk of causing NEC is extreme, and substantially deviates from consumers' and Plaintiffs' expectations.

93. Defendant failed to develop a human-based milk product that was safer for extremely premature infants and low birth-weight infants like Plaintiff A.K.

94. As a result of Defendant's cow-based formula's defective design, Plaintiff A.K. developed NEC and has continued to suffer long term problems and has needed multiple surgeries, treatments, and interventions, and will need them far into the future.

95. Defendant's cow-based formula's defective design proximately caused Plaintiff A.K.'s NEC, and proximately caused Plaintiff A.K.'s long term medical and developmental problems.

THIRD CAUSE OF ACTION
Negligence

96. Despite knowing that cow-based formula significantly increases the risk of NEC in premature infants, Defendant was careless and negligent because it failed to:

a. Collect data to determine if its products were safe for premature infants;

b. Collect data to determine when and how its products could be used safely;

c. Use the significant peer reviewed research to develop instructions and/or warnings on how and when its cow-based formula should be used in order to protect babies from NEC and its medical sequelae;

d. Develop evidence-based guidelines or instructions to decrease the risk of its cow-based formula causing NEC;

e. Provide evidence-based guidelines or instructions to decrease the risk of its cow-based formula causing NEC;

f. Stop or deter its cow-based formula from being fed to extremely premature infants like Plaintiff A.K.;

g. Provide evidence-based guidelines or instructions on when or how an extremely premature infant like Plaintiff A.K. should be transitioned to its cow-based formula;

h. Continuously and vigorously study its cow-based formula to avoid NEC in premature infants;

i. Send out letters with warnings to hospitals, NICUs, and doctors that its cow-based formula was significantly increasing the risk of NEC in premature infants like Plaintiff A.K.;

j. Send out letters with instructions to hospitals, NICUs, and doctors on when and how its cow-based formula should be used to avoid NEC;

k. Market and/or sell its products in a way which would protect premature infants like Plaintiff A.K. from NEC;

l. Provide proper training or information to health care providers for safe use of its cow-based formula;

m. Take reasonable precautions to prevent premature infants like Plaintiff A.K. from developing NEC;

n. Develop a human-milk-based premature infant formula;

o. Properly or promptly notify the FDA that its cow-based formula significantly increases the risk of NEC in premature infants like Plaintiff A.K.; and/or

p. Require or recommend that hospitals warn of the risk of causing NEC created by its cow-based formula, despite knowing that NICUs and physicians were not warning of such.

97. Defendant's negligence proximately caused Plaintiff A.K.'s NEC, and proximately caused Plaintiff A.K.'s long-term and ongoing medical problems and developmental delays.

PRAYER FOR RELIEF

98. Plaintiffs seek a judgment awarding:

a. Compensatory damages in an amount to be determined at trial;

b. Punitive damages in an amount to be determined at trial;

c. Attorneys' fees and costs of suit; and

d. All other relief the Court finds just and proper.

DEMAND FOR JURY TRIAL

99. Plaintiffs demand a jury trial on all issues so triable.

Dated: May 19, 2022

Respectfully submitted,

By: */s/ Fabrice N. Vincent*
Fabrice N. Vincent

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
Fabrice N. Vincent (CA Bar No. 160780)
fvincent@lchb.com
Ian R. Bensberg (application for admission *pro hac vice* forthcoming)
ibensberg@lchb.com
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: 415.956.1000
Facsimile: 415.956.1008

LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
Wendy R. Fleishman (N.Y. Bar No. 2500429) (*pro hac vice* anticipated)
wfleishman@lchb.com
250 Hudson Street, 8th Floor
New York, NY 10013
Telephone: 212.355.9500
Fax 212. 355.9592

Attorneys for Plaintiffs

2410794.4